PATENT COOPERATION TREATY

Medtronic P/211 PCT
51288-24 WO
P/211 WO

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference 14364-0049	Date of Mailing (day/month/year) 11 AUG 2004 REPLY DUE within 2 months/days from the above date of mailing
International application No. PCT/US03/30010	International filing date (day/month/year) 18 September 2003 (18.09.2003)
Priority date (day/month/year) 18 September 2002 (18.09.2002)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61F 2/02; A61K 47/20 and US Cl.: 424/423; 514/772.3	
Applicant MEDTRONIC VASCULAR, INC.	

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By

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.
   - **When?** See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~
   - **How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.
   - **Also** For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*. For an informal communication with the examiner, see Rule 66.6

   If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 18 January 2005 (18.01.2005)

DOCKETED
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RED BOOK
2nd Review
No Written Opinion

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	Authorized officer Carlos A. Azpuru *F. Roberts for* Telephone No. (571) 272-1600
Facsimile No. 872-9306	

Form PCT/IPEA/408 (cover sheet)(July 1998)

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PATENT DEPARTMENT
SEP 2 2004
Preston Gates Ellis

Docketed on: 9/2/04 By: MM H
C/M: 51288-24 WO Action Due: Resp WO
Reminder: 9/11/04 Due Date: 10/4/04
Drop Dead Date:

WRITTEN OPINION

International application No.
PCT/US03/30010

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	5-6, 9, 10, 14-18, 21-25	YES
	Claims	1-4, 7, 8, 11, 12, 13, 19, 20	NO
Inventive Step (IS)	Claims	5, 6, 14-18	YES
	Claims	1-4, 7 - 13, 19-25	NO
Industrial Applicability (IA)	Claims	1-25	YES
	Claims	NONE	NO

2. CITATIONS AND EXPLANATIONS
Please See Continuation Sheet

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:
The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

V. 2. Citations and Explanations:
Claims 1-4, 7, 8, 11, 12, 13, 19, and 20 lack novelty under PCT Article 33(2) as being anticipated by SCIMED LIFE SYSTEMS, INC. (WO 00/32255)

SCIMED LIFE SYSTEMS, INC. disclose a medical implant for the controllable delivery of at least one pharmaceutical to a localized area wherein said implantable medical device has a surface coating of at least two layers, at least one of the layers incorporating a releasable pharmaceutical compound, and having at least one physical property affecting the release profile of the pharmaceutical. (see page 5, lines 26-28; page 11, lines 17-29; page 13, lines 19 and 20; page 14, lines 9 and 10; page 17, line 11-27; page 21, paragraphs 14-21; claims 1, 2, 4, 8, 10). The claims are anticipated by SCIMED LIFE SYSTEMS INC.

Claims 1-4, 7-13, 19-25 lack an inventive step under PCT Article 33(3) as being obvious over SCIMED LIFE SYSTEMS, INC. (WO 00/32255) in view of CORDIS CORPORATION (WO 02/26139).

SCIMED LIFE SYSTEMS INC disclose a medical implant for the controllable delivery of at least one pharmaceutical to a localized area wherein said implantable medical device has a surface coating of at least two layers, at least one of the layers incorporating a releasable pharmaceutical compound, and having at least one physical property affecting the release profile of the pharmaceutical. (see page 5, lines 26-28; page 11, lines 17-29; page 13, lines 19 and 20; page 14, lines 9 and 10; page 17, line 11-27; page 21, paragraphs 14-21; claims 1, 2, 4, 8, 10). SCIMED LIFE SYSTEMS, INC. fails to teach the inclusion of rapamycin in such medical implants.

In another patent related to layered implantable drug delivery systems, CORDIS CORPORATION discloses that the use of rapamycin in such systems is well known at page 19, lines 2-32. As such, it would have been well within the skill of the ordinary practitioner to incorporate rapamycin into the device disclosed by SCIMED LIFE SYSTEMS, INC. and further to expect similar antiproliferative effects from the use thereof given the teachings of CORDIS CORPORATION. As such, the instant invention would have been obvious given the teachings of SCIMED LIFE SYSTEMS, INC in view of CORDIS CORPORATION.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Claims 5-6, 9, 10, 14-18, 21-25 meet the criteria set out in PCT Article 33(2), because the prior art does not teach medical implant for the controllable delivery of at least one pharmaceutical to a localized area wherein said implantable medical device has a surface coating of at least two layers, at least one of the layers incorporating a releasable pharmaceutical compound, and having at least one physical property affecting the release profile of the pharmaceutical.

Claims 5, 6, 14-18 meet the criteria set out in PCT Article 33(3), because the prior art does not teach or fairly suggest the claimed invention.

Claims 1-4, 7-13, 19-25 lack an inventive step under PCT Article 33(3) as being obvious over SCIMED LIFE SYSTEMS, INC. (WO/0032255) in view of CORDIS CORPORATION (WO 02/26139).

SCIMED LIFE SYSTEMS, INC. disclose a medical implant for the controllable delivery of at least one pharmaceutical to a localized area wherein said implantable medical device has a surface coating of at least two layers, at least one of the layers incorporating a releasable pharmaceutical compound, and having at least one physical property affecting the release profile of the pharmaceutical. (see page 5, lines 26-28; page 11, lines 17-29; page 13, lines 19 and 20; page 14, lines 9 and 10; page 17, line 11-27; page 21, paragraphs 14-21; claims 1, 2, 4, 8, 10). SCIMED LIFE SYSTEMS INC fails to teach the inclusion of rapamycin in such medical implants.

In another patent related to layered implantable drug delivery systems, CORDIS CORPORATION discloses that the use of rapamycin in such systems is well known at page 19, lines 2-32. As such, it would have been well within the skill of the ordinary practitioner to incorporate rapamycin into the device disclosed by SCIMED LIFE SYSTEMS, INC. and further to expect similar antiproliferative effects from the use thereof given the teachings of CORDIS CORPORATION. As such, the instant invention would have been obvious given the teachings of SCIMED LIFE SYSTEMS, INC. in view of CORDIS CORPORATION.

Claims 1-25 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry as an implantable drug delivery system.

WRITTEN OPINION

International application No.
PCT/US03/30010

I. Basis of the opinion

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☒ the description:
pages 1-17, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages 18-20, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the drawings:
pages 1/4 -4/4, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."*